

AD _____

USAARL REPORT NO. 74-10

SOFT (HYDROPHILIC) CONTACT LENSES IN U. S. ARMY AVIATION:
AN INVESTIGATIVE STUDY OF THE BAUSCH AND LOMB SOFLENSTM

BY

John K. Crosley, O.D., M.S.,	MAJ, U.S. Army
Erwin G. Braun, O.D., M.S.,	MAJ, U.S. Army
Robert W. Bailey, O.D., M.S., Ph.D. (candidate),	COL, U.S. Army

March 1974

U. S. ARMY AEROMEDICAL RESEARCH LABORATORY

Fort Rucker, Alabama



Unclassified

ADA776353
Technical Report

Security Classification

DOCUMENT CONTROL DATA - R & D

(Security classification of title, body of abstract and indexing annotation must be entered when the overall report is classified)

1. ORIGINATING ACTIVITY (Corporate author) U. S. Army Aeromedical Research Laboratory Fort Rucker, Alabama		2a. REPORT SECURITY CLASSIFICATION Unclassified	
		2b. GROUP	
3. REPORT TITLE SOFT (HYDROPHILIC) CONTACT LENSES IN U.S. ARMY AVIATION: AN INVESTIGATIVE STUDY OF THE BAUSCH AND LOMB SOFLENSTM			
4. DESCRIPTIVE NOTES (Type of report and inclusive dates)			
5. AUTHOR(S) (First name, middle initial, last name) John K. Crosley, MAJ, MSC Erwin G. Braun, MAJ, MSC Robert W. Bailey, COL, MSC			
6. REPORT DATE March 1974		7a. TOTAL NO. OF PAGES 18	7b. NO. OF REFS 4
8a. CONTRACT OR GRANT NO.		9a. ORIGINATOR'S REPORT NUMBER(S) USAARL Report No.	
b. PROJECT NO. 3A762758A 819			
c. Work Unit No. 50 - (FY 74)		9b. OTHER REPORT NO(S) (Any other numbers that may be assigned this report)	
d.			
10. DISTRIBUTION STATEMENT This document has been approved for public release and sale; its distribution is unlimited.			
11. SUPPLEMENTARY NOTES		12. SPONSORING MILITARY ACTIVITY U.S. Army Medical R & D Command Washington, D.C. 20314	
13. ABSTRACT The use of standard acrylic or "hard" contact lenses has been relatively unsuccessful in the military aviation environment, particularly when worn by personnel flying rotary wing aircraft. The purpose of this study was to evaluate the applicability of one type of hydrophilic lens to U.S. Army aviation. Nineteen volunteer helicopter pilots served as subjects and three specific areas were investigated. These were: (1) clinical procedures, (2) foreign body involvement, and (3) the effect of extended (72 hours) continuous wear. The results indicate that the Soflens TM offers certain advantages over acrylic lenses for this specialized application. There were, however, distinct problems encountered which may be lessened with the introduction of new lens materials and asepticizing techniques.			

DD FORM 1473, 1 JAN 64, WHICH IS
REPLACES DD FORM 1473, 1 JAN 64, WHICH IS
OBSOLETE FOR ARMY USE.

Unclassified

Security Classification

14	KEY WORDS	LINK A		LINK B		LINK C	
		ROLE	WT	ROLE	WT	ROLE	WT
	1. Contact Lenses						
	2. Vision						
	3. Aviation Vision						
	4. Soft Contact Lenses						
	5. Hydrophilic Contact Lenses						
	6. Eyes						
	7. Visual Acuity						

NOTICE

Qualified requesters may obtain copies from the Defense Documentation Center (DDC), Cameron Station, Alexandria, Virginia. Orders will be expedited if placed through the librarian or other person designated to request documents from DDS (formerly ASTIA).

Change of Address

Organizations receiving reports from the U.S. Army Aeromedical Research Laboratory on automatic mailing lists should confirm correct address when corresponding about laboratory reports.

Disposition

Destroy this report when it is no longer needed. Do not return it to the originator.

Distribution Statement

This document has been approved for public release and sale; its distribution is unlimited.

Disclaimer

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

AD _____

USAARL REPORT NO. 74-10

SOFT (HYDROPHILIC) CONTACT LENSES IN U. S. ARMY AVIATION:
AN INVESTIGATIVE STUDY OF THE BAUSCH AND LOMB SOFLENSTM

BY

John K. Crosley, O.D., M.S.,	MAJ, U.S. Army
Erwin G. Braun, O.D., M.S.,	MAJ, U.S. Army
Robert W. Bailey, O.D., M.S., Ph.D. (candidate),	COL, U.S. Army

March 1974

U. S. ARMY AEROMEDICAL RESEARCH LABORATORY

Fort Rucker, Alabama

U. S. Army Medical Research and Development Command

Distribution Statement. This document has been approved
for public release and sale; its distribution is unlimited.

ACKNOWLEDGMENT

The authors wish to extend their sincere appreciation to the U.S. Army aviators who volunteered their time to serve as subjects for this study and to the Bausch and Lomb Optical Company for furnishing the ophthalmic materials.

ABSTRACT

The use of standard acrylic or "hard" contact lenses has been relatively unsuccessful in the military aviation environment, particularly when worn by personnel flying rotary wing aircraft. The purpose of this study was to evaluate the applicability of one type of hydrophilic lens to U.S. Army aviation. Nineteen volunteer helicopter pilots served as subjects and three specific areas were investigated. These were: (1) clinical procedures, (2) foreign body involvement, and (3) the effect of extended (72 hours) continuous wear. The results indicate that the SoflensTM offers certain advantages over acrylic lenses for this specialized application. There were, however, distinct problems encountered which may be lessened with the introduction of new lens materials and asepticizing techniques.

APPROVED:

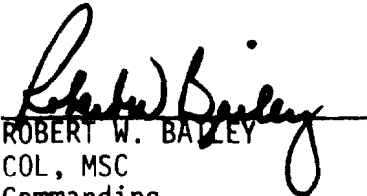

ROBERT W. BAILEY
COL, MSC
Commanding

TABLE OF CONTENTS

	Page
<u>INTRODUCTION</u> -----	1
<u>METHODOLOGY</u> -----	5
<u>RESULTS AND DISCUSSION</u> -----	8
<u>CONCLUSIONS AND RECOMMENDATIONS</u> -----	14
<u>Literature Cited</u>	16
Appendix I - <u>QUESTIONNAIRE</u>	A-1
DD Form 1473	

SOFT (HYDROPHILIC) CONTACT LENSES IN U.S. ARMY AVIATION:
AN INVESTIGATIVE STUDY OF THE BAUSCH AND LOMB SOFLENSTM

INTRODUCTION

The advantages of contact lenses in lieu of regular spectacles in the military environment are numerous, particularly in aviation. Provided an adequate contact lens could be found, the soldier and the military aviator requiring corrective lenses would benefit in such ways as:

1. Improved visual performance outside aircraft in inclement weather.
2. Reduction of lost or broken spectacles.
3. No lens fogging.
4. Elimination of annoying reflections from the rear of the lens.
5. No revealing reflections as can occur from the front surface of a spectacle lens in a combat situation.
6. No mechanical or optical interference when using optical equipment, such as sighting devices.
7. Elimination of the broken glass hazard.
8. No spectacle lens smear or dirt accumulation acquired while performing tasks in unclean environments.
9. Perspiration problems eliminated.
10. Instant compatibility with gas mask.
11. Increased visual field.
12. Improved visual acuity over spectacle lenses in specific cases.
13. Improved acoustic protection and increased comfort with the elimination of spectacle temples when wearing a helmet.

McGraw and Enoch¹, in the only previously published paper reporting on contact lenses within the Army environment, found distinct disadvantages with the hard plastic and glass contact lenses they investigated. These included expense, irritation to the eye, time required to properly prescribe the lenses, lack of adequately trained professional personnel (no longer deemed a serious problem), temporary changes in the corneal physiology, individual tolerance levels, photophobia and foreign body involvement.

Rengstorff² found that 99 percent of U.S. Army basic trainees wearing polymethyl methacrylate (PMMA) lenses and exposed to dust, sand, and other offensive materials reported irritation from these materials. In another study³, he estimated the number of contact lens wearers in the U.S. Army at "probably higher than three percent".

More recently, the U.S. Air Force has been successfully fitting PMMA contact lenses on selected aircrew members because of the non-compatibility of spectacles with certain in-flight requirements. Based upon the study by McGraw and Enoch, and due to differences between Army and Air Force aviation requirements, a program modeled after the Air Force program has not been considered appropriate for Army aviation.

Hydrophilic lenses appear to have a possible application in aviation as a means of correcting ametropia in selected Army aircrew. It is of interest here to note that, in 1968, the vision standards for entry into primary flight training were altered to accept candidates with a limited degree of refractive error. This program is still active for selected personnel. Additionally, a certain percentage of rated aviators will develop a need for corrective lenses as they progress through their careers. This research investigation was designed to evaluate the physiological and environmental differences of the soft contact lens compared to the known unacceptable features of the PMMA lens as they relate to U.S. Army aviation application. Correspondence with the Air Force and Navy indicates that they have no similar investigation ongoing at present, but both services expressed interest in the results of this study.

Although newer materials are presently being investigated, currently the only contact lens to receive Food and Drug Administration approval for ametropic application is the Bausch and Lomb SoflensTM. The material⁴ for this lens is poly(2-hydroxyethyl methacrylate) and was originally developed in Czechoslovakia. These lenses are made by polymerizing a monomer solution in a

spinning mold which forms a spherical convex and an aspheric concave surface. The finished lens is a hemispherical shell of approximately 13 millimeter (mm) chord diameter and 0.1 and 1.0 mm thickness. It consists of 61.4 percent poly(2-hydroxyethyl methacrylate) and 38.6 percent water by weight when immersed in normal (.9%) physiologic saline solution. In the hydrated state, this lens becomes soft and pliable. When placed on the human cornea the hydrated lens acts as a refracting medium to compensate essentially spherical ametropias. The material has a refractive index of 1.43 and the finished lens has a visible light transmittance of approximately 97 percent.

The SoflensTM is manufactured in three series: F, N, and C. The anterior lens surface has the same radius of curvature for all lenses in a given series. The posterior central lens surface radius is varied to provide power ranges. The anterior curvature is the same (8.2 mm) for the C and N series, but is 8.8 mm for the F series. The overall lens diameter is the same for the F and N series (12.5 mm), but is 13.5 mm for the C series. The lens thickness is also the same (0.17 mm) for the F and N series, but varies (.09 to .36 mm) for the C series.

Power verification for these lenses is particularly important since differences have been found in the vial-marked power and the actual power. Perhaps the easiest method to determine power is by blotting the lens several times while holding it with the plastic-tipped tweezers provided by the manufacturer and allowing it to air-dry for approximately thirty seconds. Placing the convex surface on the objective of the lensometer or vertometer, the power can be read within 0.25 diopters.

Bausch and Lomb recommends that their lens be utilized for the correction of visual acuity in persons with non-diseased eyes who have spherical ametropias, refractive astigmatism of 1.50 diopters or less and/or corneal astigmatism of 2.00 diopters or less.

Use of the SoflensTM is contraindicated by the presence of any of the following conditions:

1. Acute and subacute inflammations of the anterior segment of the eye.
2. Any eye disease which affects the cornea or conjunctiva.
3. Insufficiency of lacrimal secretion.
4. Corneal hypoesthesia.

5. Any systemic disease which may affect the eye or be exaggerated by wearing contact lenses.

The lenses should not be worn while swimming, since they may be washed from the eye, absorb chlorine (if present), or the water may reduce the saline content and cause a temporary hypotonic state. Should the lenses become hypotonic while on the eye, they may be impossible to remove until the eye has replaced the sodium chloride (salt) through copious tearing or saline has been added topically. An additional problem may occur if the lenses are worn in the presence of noxious or irritating vapor, since they may be absorbed into the lens material and become concentrated. This concentration adjacent to the cornea could cause changes in the normal corneal physiology and create a potentially dangerous situation if allowed to exist.

The lenses are normally stored in a container designed to keep them immersed in normal saline. If left exposed to air, the lenses will dehydrate, become brittle, and break easily. Should dehydration occur, soaking in saline will quickly reestablish hydration with no subsequent change in optical quality.

SoflensTM cleaning must be accomplished daily and is normally done by holding the lens between the fingers, or in the palm and rubbing while rinsing with saline solution. This procedure is necessary to remove mucus and film from the lens surface. It is also recommended that twice weekly they be held under tepid tap water and rubbed briskly since this will aid in removing more stubborn dried protein, etc. Afterward, they should be rehydrated with saline. In addition to cleaning, it is necessary to asepticize (so-called because this process does not result in a true sterilization), using a unit provided by the manufacturer. This unit, not unlike a baby bottle warmer, is designed to automatically boil distilled water with the lens-containing case submerged and then automatically shut off after a short period of time. Distilled water is highly recommended to reduce the accumulation of mineral salts in the boiling unit. Regular (daily) use of this asepticizer unit is claimed to prevent the growth of staphylococcus aureus, pseudomonas aeruginosa, bacillus subtilis, candida albicans, and herpes simplex on the lens and in the carrying case.

The storage case is designed to hold two lenses and keep them hydrated in saline solution. This solution must be changed daily and the case must be cleaned under tap water once a week. The case is designed to snap into the underside of the asepticizer top. In a situation where the asepticizer unit (or electricity) is not available, the case containing the lenses and saline can be dropped into a

pan of boiling tap water for fifteen minutes. This supposedly is as effective as using the asepticizer unit.

Personal hygiene is important with these lenses. The hands should be washed and dried with a lint-free towel before handling them. In addition, care should be taken to avoid bringing the lenses in contact with cosmetics, lotions, soaps and creams. Hair spray should be allowed to settle before opening the eyes, since the mist in the air could attach to the anterior lens surface.

Standard fluorescein, often used in conjunction with PMMA contact fitting, cannot be used while the soft contact lenses are in the eye since the material will absorb the dye. The usual procedure is to have the patient remove the lenses, instill the fluorescein, flush the eyes with saline when finished, and wait one hour before replacing the lenses.

Adverse reactions with the soft lenses are relatively rare. Serious corneal damage may result if the lenses are soaked in a conventional contact lens solution containing preservatives, and then worn. On occasion, eye irritation may result if a hypertonic lens is placed on the eye. This can be relieved by simple removal of the lens. Placing a hypotonic lens on the eye or perhaps routinely sleeping with the lenses in place can possibly cause them to abnormally adhere to the cornea. Should this occur, removal can be accomplished by applying a few drops of normal saline, waiting a few minutes for the lenses to loosen, and removing in the normal manner. Rarely, individuals will exhibit a reduced tear flow (so-called "dry eye") which makes them a poor risk for any type of contact lens.

Care should be exercised during insertion and removal, since the lenses can be torn when handled improperly. If dropped, the lenses are particularly difficult to find. Should they not be located in a very short time, they will have dehydrated and will be quite fragile. The safest procedure, should this occur, is to rehydrate with normal saline prior to touching.

METHODOLOGY

This study was designed specifically to provide information in three areas and was thus divided into three phases.

Phase I dealt with the clinical aspects of the lenses. Phase II was concerned with the incidence rate of foreign body involvement, since this is considered to be a prime factor contraindicating the

use of PMMA contact lenses in aviation. This is particularly true when they are worn in the rotary-wing aircraft environment. Phase III was designed to provide information about continuous wear for an extended period. The rationale for this portion of the investigation lies in the mission requirements frequently encountered in a combat situation. Due to these requirements, the aviator is often unable to achieve sufficient rest which can have an adverse effect on the wearing of PMMA contact lenses. The time frame defining extended operations is based upon physiological and psychological limits of the individual. It is assumed that if the lenses can be worn continuously with reasonable comfort for a 72-hour period, they satisfactorily fulfill the operational requirement.

A. Subjects

Subjects were nineteen U.S. Army aviators who (1) were required to fly a minimum of 15 hours per month, (2) had at least 6 months (to the best of their knowledge) remaining at Fort Rucker, Alabama, (3) wore corrective minus lenses with not more than 2.00 diopters of corneal astigmatism, and (4) were free of active ocular pathology.

B. Instrumentation and Materials

1. Phoropter (for determining refractive error)
2. Chart projector
3. Ophthalmometer (for measuring corneal curvature)
4. Biomicroscope (slit lamp) with polaroid adapter used to inspect the anterior portion of the eye microscopically.
5. Retinoscope (for objectively determining the refractive error)
6. Ophthalmoscope (for evaluating any changes within the eye)
7. Modified SoflensTM fitting set containing 72 finished lenses with professional aseptor unit. The modified set had no minus lenses above 4.00 diopters, and no plus lenses.
8. A personal "care kit" for each subject, consisting of an asepticizing unit, sodium chloride U.S.P. tablets (250 mg.), carrying case, distilled water with two plastic bottles for preparing and carrying normal saline solution, and instruction booklet.

9. Projector and cassette movie showing lens insertion, removal, and daily care.

10. Keratoscope (Placido's Disc)

C. Clinical Procedure

The following steps were performed with each patient to insure uniformity of professional care and to determine those clinical aspects which were deemed acceptable or unacceptable for application to aviation.

1. Internal and external ocular examination to eliminate physiological complications.

2. Patient case history which included questions pertaining to the psychological implications of wearing the lenses.

3. Visual examination to determine best visual acuity, binocular balance, and eye dominance.

4. Keratometry.

5. During the initial visit, subjects were fitted with contact lenses from the practitioner trial set. The first lenses inserted were determined by reference to a selection chart provided by the manufacturer. This chart was used as a guideline and took into consideration the physical characteristics of the lenses as they related to the subject's prescription and corneal curvature.

6. During a subsequent 30 minute period of lens adaptation, the subjects were shown a movie which outlined the proper procedure for lens insertion, removal and daily care. This was later verbally emphasized and expanded by the investigators.

7. Approximately 20 minutes following lens insertion, the lens-cornea relationship was evaluated by the following technique:

a. Lens centering, movement and corneal integrity were determined by biomicroscopy. Particular care was taken to determine that the flow of blood cells through scleral blood vessels was unobstructed in regions where the lens edge was located.

b. An over-refraction was performed and the quality of the light reflex determined by retinoscopy.

c. A keratoscope was used to evaluate the contact lens fit by observing the quality of the concentric rings.

d. Visual acuity was determined using the standard projected Snellen letters.

8. At this point, the lenses were removed and the biomicroscopic portion of the examination repeated. If there was any indication of corneal epithelial disturbance, fluorescein (strip) was used to better identify the extent. Subsequent to the use of fluorescein, the eye(s) was irrigated with normal saline prior to lens reapplication.

9. The lenses were then reinserted by the subject, and removed by him, with the investigator providing guidance. Proper lens care was reemphasized at this point.

10. Four days after the initial visit, the subjects were re-examined according to 7 above, and once every two weeks thereafter for a period of six months. Additional visits were individually scheduled according to need.

The procedures for Phase III (continuous wear for 72 hours) involved a careful case history, macroscopic examination, microscopic (slit lamp) examination, ophthalmoscopy and visual acuity determination. These procedures were accomplished at 24, 32, 48, 56 and 72 hours by a team consisting of an optometrist and an ophthalmologist. The subjects were instructed to wear the lenses continuously with the exception that they could remove and clean them at any time if they felt the need for it. They were also instructed to contact the investigators should any problems arise at any time, day or night. Since the subjects were not allowed to fly during this period, the number participating was small. The program began upon arising on Day 1, and the first examination accomplished at 0800 hours, Day 2; the second at 1600 hours, Day 2; the third at 0800 hours, Day 3; the fourth at 1600 hours, Day 3; and the last at 0800 hours, Day 4.

RESULTS AND DISCUSSION

PHASE I

As noted, Phase I dealt with the clinical aspects of these particular lenses. We were interested in determining what, if any, peculiar problems might arise and what effect they might have in reference to the aviation environment. It is not unreasonable to assume that the majority of these problems are equally applicable to most other military environments.

One difficulty encountered quite early in the program was scheduling subjects. It was frequently necessary to juggle schedules to allow for sickness, temporary duty (TDY), work schedules, and flying duties. As in most clinics, there were the normal missed appointments due to misunderstandings and forgetfulness. Scheduling was further complicated due to necessary TDY performed by the investigators.

Two subjects each lost one lens during the program. This was, however, apparently due to poor insertion technique.

One subject was accepted for the program, although his astigmatic error (2.00 diopters corneal) made him a high risk. In spite of reasonable success in terms of lens fit, this subject was unable to tolerate a rather large depreciation of visual acuity (2 to 3 lines) and asked to be dropped from the program.

The remaining eighteen subjects were able to wear their lenses for the normal waking hours following an adaptation period averaging four days. There is reason to believe that even this period could have been shortened without causing adverse effects.

The mean flying time accomplished by the subjects was 20 hours per month, with approximately 90 percent being daytime and 10 percent nighttime.

At least 20/20 visual acuity was achieved with all subjects except the one with 2.00 diopters cylindrical correction. There were, however, some subjects who reported that the 20/20 line was not absolutely distinct. These same subjects would often report that their distance visual acuity with the lenses in place would vary. Visual acuity was reported to be noticeably worse during periods of general fatigue and/or in the presence of sinus congestion.

Subjects generally tended to be acutely aware of slight differences in visual acuity or lens comfort between the two eyes.

Near vision problems were encountered early in the program. It was found, however, that after the proper lens had been selected and the near vision balanced, these complaints were essentially eliminated. There were two subjects (one pre-presbyope age 39, and one presbyope age 44) who had more difficulty than the others achieving distance and near balance. The 44 year old subject became discouraged with the lenses and ultimately dropped from the program.

PHASE II

Phase II was specifically designed to determine the frequency of foreign body involvement while functioning in the aviation environment. This hazard was increased by selecting the majority of subjects from the rotary-wing (helicopter) population. It was assumed that if the subject could function adequately around the rotor wash area of the helicopter, he would not be likely to encounter a more adverse situation. Ninety-five percent of the accrued flight time was rotary-wing.

None of the subjects reported any instances of foreign bodies under their contact lenses at any time throughout the study.

Considering the results of this study and reports in the literature, it appears that the problem with foreign bodies is essentially eliminated by this type of lens. However, it must be pointed out that should an aviator wearing contact lenses encounter a foreign body while in the act of flying, he must be prepared to "tough it out" until he can land or transfer aircraft control to a copilot. There is an excellent probability that if the lens can be removed in flight and the eye irrigated, the problem can be resolved. Of course, this same problem can present itself in flight even if he is not wearing contact lenses. It could even be worse, since he is unlikely to have a bottle of normal saline available for irrigation.

PHASE III

Phase III, as noted earlier, was designed to evaluate continuous (72 hours) wearing of this lens. There were a total of 6 subjects participating, with one subject, J.B., being dropped due to a requirement to fly during this period. To preclude any unnecessary risk, none of the subjects flew during Phase III.

24 Hours (0800 hours, Day 2)

Subject T.C.

Vision "somewhat hazy" when awoke - removed, cleaned, reinserted lenses with no apparent problem other than slight nearpoint irregularity - slit lamp (SL) and ophthalmoscopy (O) negative - visual acuity (VA): OD 20/20 OS 20/20.

Subject T.P.

Vision slightly hazy upon awakening - removed, cleaned and reinserted lenses with no further problem - SL and O negative - VA: OD 20/20 OS 20/20.

Subject A.M. (OD lens only)

Required only a monocular (O.D.) lens to correct ametropia - lens "stuck to eye" upon awakening - was hesitant about removing until after visit during which time he was reminded about the application of normal saline to reverse hypotonicity - OD slightly injected, but was cleared to continue wearing during program - SL and O negative - VA: OD 20/20 OS 20/20.

Subject R.W.

Incurred no problem other than slight haziness upon arising - did not remove and haze cleared spontaneously after 20 to 30 minutes. SL and O negative - VA: OD 20/20 OS 20/20.

Subject T.Mc.

Noted slight burning sensation after retiring to bed - cleared shortly thereafter - had slight haze when first awoke - cleaning resolved the problem. SL and O negative - VA: OD 20/20 OS 20/20.

48 Hours (0800 hours, Day 3)

Subject T.C.

"Vision was blurry when I awoke this morning" - subject's vision was cleared by removing and cleaning lenses - he also noted some photophobia which disappeared after approximately two hours. VA: OD 20/20 OS 20/20 - SL and O negative.

Subject T.P.

Vision somewhat blurred upon arising - removed and cleaned lenses - vision slightly hazy without lenses - vision still slightly hazy after lenses reinserted - after wearing lenses one hour vision was hazy. VA: OD 20/20 fair OS 20/15. SL showed OD slightly edematous, OS normal - O: negative.

Subject R.W.

Vision slightly blurred upon awakening - cleared to normal after lenses removed, cleaned, and reinserted - VA, SL and O normal.

Subject A.M. (OD lens only)

VA: OD 20/40 - by moving lens around was able to improve to fair 20/20, but blurred again after blinking - SL showed slight corneal

injection - cornea appearance improved over previous examination - OD "was burning last night" - vision upon arising was not as "cloudy" as previous day - vision cleared much better after cleaning this morning. O: negative.

Subject T.Mc.

Necessary to remove lenses at 2330 hours shortly after retiring because of burning sensation - left lenses off remainder of night - reinserted lenses this morning at 0730 hours after cleaning them well - no further problems encountered. VA: OD 20/20⁻, OS 20/20⁺. SL: corneas clear, heavy mucus accumulation, some "debris" on OD - movement and centering normal. O: negative.

56 Hours (1600 hours, Day 3)

Subject T.C.

Lenses riding somewhat low and slightly temporal, particularly OS - considerable circumcorneal injection - corneas show a slight haziness - "Lenses feel good, no problem" - VA: OD 20/20 OS 20/20⁺. SL and O: negative.

Subject T.P.

Subject spent 10 minutes in sauna at 160 degrees Fahrenheit with lenses in place and experienced no problems. SL - corneas appear normal except for some circumcorneal injection - both lenses riding high and temporal - lens movement is normal. VA: OD 20/20⁺ - OS 20/20⁺. O: negative.

Subject A.M. (OD lens only)

Lens feels generally good, but eye itches after lens removal. SL - lens rides temporally and movement generally inadequate - small punctate area of stippling on cornea at 5 o'clock, eye appears injected. VA: OD 20/25⁺ with slight fuzziness. O: negative.

Subject R.W.

Lenses feel dry occasionally, but relief obtained by closing eyes for short period - lenses generally feel comfortable and vision seems normal. SL: lenses center well, but both corneas exhibit slight edema with considerable circumcorneal injection. VA: OD 20/20⁺ OS 20/20⁺. O: negative.

Subject T.Mc.

After two or three hours, subject reports a slight intermittent burning sensation. SL: lenses center well and movement is good - corneas look clear, but there appears to be excessive mucus secretion and accumulation which could possibly impede tear flow - there is moderate scleral injection. VA: OD 20/20- OS 20/20+. O: negative.

72 Hours (0800 hours, Day 4)

Subject T.C.

Lenses still riding slightly low and temporal; OS more than OD. Removed and cleaned lenses upon arising. VA: OD 20/20+ OS 20/20. SL: slight circumcorneal injection. O: negative.

Subject T.P.

Lenses still riding somewhat high and temporal with good movement. Had some slight mucus OU upon arising - cleaned and reinserted with no subsequent problems. VA: OD 20/20+ OS 20/20+. SL: some circumcorneal injection, but not considered excessive - good lens movement. O: negative.

Subject R.W.

Vision somewhat blurred upon arising - eyes felt rather sensitive - reported considerable mucus which was washed away with saline - no subsequent problem with mucus or sensitivity - VA: OD 20/20+ OS 20/20+. SL: showed some conjunctival injection, but not excessive. O: negative.

Subject A.M. (OD lens only)

Lens somewhat uncomfortable upon arising - removal alleviated discomfort - left lens off for approximately one hour - reinsertion accomplished, but lens did not feel totally comfortable. VA: OD 20/25+ OS 20/20. SL: considerable injection with some small punctate stippling at approximately five o'clock. O: negative. Decision made to leave lenses off for 24 hours before attempting to wear again.

Subject T.Mc.

Lenses slightly uncomfortable when went to bed - decided to leave in all night - rather heavy mucus accumulation upon arising - removed lenses, cleaned, and irrigated eyes to relieve dryness

sensation and remove mucus - lenses burned slightly for approximately one hour after reinsertion, but reasonably comfortable now. VA: OD 20/20⁻¹ OS 20/20 (OD slightly fuzzy). SL: corneas appear clear - some mucus in OD - movement and centering good - some conjunctival injection. O: negative.

Based upon this initial study, it appears that properly fitted aviation personnel can tolerate hydrophilic contact lenses for an extensive period of continuous wear. It is apparent, however, that certain individuals are more tolerant than others in regards to long-term lens wear. As noted, these subjects were allowed to remove their lenses for cleaning as needed.

CONCLUSIONS AND RECOMMENDATIONS

Although somewhat limited in scope and number of subjects utilized, this study provides the basis for certain conclusions concerning the use of the SoflensTM in U.S. Army aviation.

1. We must be concerned about any adverse changes in visual acuity, even though they may be only transient. This is especially true as greater demands are placed upon the visual capabilities of the crewmembers. A good example would be the recent emphasis upon very low (nap-of-earth) flight under low light levels and high stress conditions. Rapid transition from the outside environment to the aircraft instruments or a map display must be accomplished quickly and without error by the pilot and copilot/navigator.

2. Flight under stress, particularly at night, could result in a decreased blink rate due to the tendency to stare. This may increase the probability of lens dehydration.

3. It is not unusual for pilots to experience extreme temperature variations. Since this potential problem was not addressed in this study, it is recommended that the lenses be evaluated under varying climatic conditions. In the region where this study was conducted, the temperature (90 to 98 degrees) and humidity (90 to 100 percent) were quite high. Perspiration is a constant problem for aviators wearing spectacles under these conditions. The contact lenses not only eliminated this problem, but the salinity of the tears reportedly aided in maintaining proper lens tonicity.

4. SoflensTM cannot be recommended for "across the board" application to all ametropic U.S. Army aviators. It is apparent,

however, that selected aviators could wear this lens comfortably and perform their required mission provided they: received proper professional care; had access to distilled water; and followed recommended wearing and cleansing procedures.

5. With the increasing sophistication in military aviation equipment, items are being developed which are not compatible with spectacle frames. To avoid a compromise some positive action must be taken. Alternatives are:

a. Design the equipment to accommodate the spectacles or incorporate the spectacle power.

b. Restrict the use of such equipment to non-spectacle wearers.

c. Eliminate all ametropic aviators or,

d. Provide satisfactory contact lenses.

6. One of the major objections to the use of PMMA lenses in aviation (foreign body involvement) has not been identified with the use of soft lenses.

7. Aviator response to the use of contact lenses is very enthusiastic.

8. Clinical results and operational evaluation indicate that the use of hydrophilic lenses present no insurmountable problems. Lens drying should receive further investigation to determine if it can be reduced or eliminated. It should also be noted that subjects who rode motorcycles reported the drying problem, particularly if they did not wear a visor or goggles while riding.

9. Long-term (in excess of eighteen hours per day) wear of this lens is not recommended. It has been shown, however, that the probability of significant problems arising from an occasional overwear is rather remote.

LITERATURE CITED

1. McGraw, J.L., and Enoch, J.M., "Contact Lenses: An Evaluation Study," U.S. Army Medical Research Laboratory, Fort Knox, KY. Report No. 99, 10 October 1952.
2. Rengstorff, R.H., "Contact Lenses and Basic Training in the U.S. Army," Military Medicine, Vol. 130, No. 4, April 1965.
3. Rengstorff, R.H., "Spectacles and Contact Lenses: A Survey of Military Trainees," Military Medicine, Vol. 130, No. 4, 13-14, January 1972.
4. Bausch and Lomb, Inc., "SoflensTM Fitting Guide: Instructions and Data on Soflens", Rochester, NY, 1971

APPENDIX I
QUESTIONNAIRE

1. Do you find your day or night vision affected by the contact lenses?

- a. No difference between contact lenses and regular spectacles during day or night (13 or 71%).
- b. Vision better at night with spectacles (3 or 16%).
- c. Both day and night vision better with contact lenses (1 or 6%).
- d. Night vision better with contact lens and day vision about the same (1 or 6%).

2. Did you notice any tendency for the lenses to become dry while being worn?

- a. Eleven subjects (61%) reported that direct air currents produced a temporary drying effect which manifested a slight burning sensation. They were generally the subjects who logged the most flight time.
- b. Two subjects (11%) stated that at times they noted a drying effect associated with abrupt temperature changes such as going outdoors from an air-conditioned building, or vice versa.
- c. One subject (6%) reported drying and discomfort on occasion as a result of high temperature in the aircraft.
- d. The remainder (22%) reported no problems.

3. Do you prefer to wear these contact lenses or regular spectacles, and why?

- a. Thirteen subjects (72%) preferred the contact lenses because they were more compatible with flight equipment, their vision was better, they sensed an improvement in their depth perception, and, they were more convenient.

b. Five subjects (28%) selected regular spectacles because of better (clearer) vision, fewer problems with near vision (particularly presbyopia), and they were annoyed by the drying tendency of the contact lenses.

4. Do you consider the asepticizing process too time consuming and bothersome?

a. Sixteen of the subjects (90%) responded negatively to this question. The majority deemed the requirement for distilled water more of a problem especially in a combat situation.

b. Two (10%) replied that asepticizing was an inconvenience.